K023092

510(k) Summary of Safety and Effectiveness

BD K-4000™ Microkeratome System

OCT 1 8 2002

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: BD Ophthalmic Systems
  411 Waverley Oaks Rd
  Building 2, Suite 229
  Waltham, MA 02452-8405
- Registration Number: 1211998
- Contact Person: Eileen T. Schweighardt
  Regulatory Affairs Manager
  Telephone no.: 201-847-4570
  Fax No. 201-847-4881
- Date of Summary: September 17, 2002

Device

- Trade Name: BD K-4000™ Microkeratome
- Classification Name: Keratome
- Classification: Class I reserved
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting Substantial Equivalence

• Device Description

The BD K-4000™ Microkeratome System is a battery operated, fully automated Keratome. The Microkeratome is a precise cutting device uniquely designed for added comfort, speed and accuracy. The Microkeratome's unique shape is designed to offer more comfort and efficiency while delivering precision and accuracy.

The BD K-4000™ Microkeratome major components are:

- Console containing the motor drive and control circuitry, Vacuum system and battery power source
- Front Panel controls for operating the system;
- Surgical Handpiece connected to the console by multi-conductor cable
- Vacuum tubing set;
- Two pedal Footswitch for actuation of the handpiece and vacuum system;
- External Battery Charger.

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- Intended Use

The BD K-4000™ Microkeratome System is a battery powered device intended to produce a corneal resection for refractive laser applications and procedures in Ophthalmic surgery, such as Laser In-situ Keratomileuses (LASIK) surgery.

- Synopsis of Performance Study Results

Performance studies were done to show the performance and equivalence of the principal devices to the predicate devices currently marketed in the United States.

All results from the studies show equivalence between the principal devices and the predicate devices. Therefore, the K-4000 is substantially equivalent to the predicate devices.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, materials, intended use and performance, the BD K-4000™ Microkeratome is shown to be substantially equivalent to the commercially available predicate devices indicated in the table below. The predicate devices, K number, and clearance date are also identified in the table below.

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson	BD K-3000™ Microkeratome	K984537	Sept. May 14, 1999
	BD K-3000™ Microkeratome (expanded claims for LASIK)	K022637	Pending

Eileen T. Schweighardt

10/17/02.

Eileen T. Schweighardt
Regulatory Affairs Manager
B D Ophthalmic Systems
Becton Dickinson and Company

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Becton, Dickinson and Company
c/o Eileen T. Schweighardt
Regulatory Affairs Manager
1 Becton Drive
Franklin Lakes, NJ 07417

OCT 18 2002

Re: K023092
Trade/Device Name: BD K-4000™ Microkeratome System
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HMY
Dated: September 17, 2002
Received: September 18, 2002

Dear Ms. Schweighardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known) K023092

Device Name BD K-4000™ Microkeratome System

Indications for Use

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PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K023092

Prescription Use √ OR Over-The Counter Use ——
(per 21 CFR 801.109)